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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,389	12/05/2003	Kevin Smith	SYN-8312	9231
27316 7590 06/13/2008 MAYBACK & HOFFMAN, P.A. 5722 S. FLAMINGO ROAD #232 FORT LAUDERDALE, FL 33330				
EXAMINER				
WOO, JULLAN W				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/728,389

Applicant(s)

SMITH ET AL.

Examiner

Julian W. Woo

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) 67-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-66 and 83-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker (2,108,206) in view of Heil, Jr. et al. (5,514,174), and further in view of Ley (5,514,076). Meeker discloses the invention substantially as claimed. Meeker discloses, at least in the figures and in col. 1, line 51 to col. 2, line 41; a retractor including a rigid body (1); a retraction device for manipulating or grasping an object, where the device has a head (2, 3, or distal portion of 1) connected to the distal end of the body; two, flexible needles (4a or 4b) of resilient metal; and a removable actuation device (9) connected to the proximal end of the body; where the body has a longitudinal extent, where the head is connected removably or integrally formed (i.e., integrated) with the body; where the head has two head halves (i.e., the head is symmetrical with respect to a longitudinal axis and can be defined by two halves formed together) and defines tracks (5a), which have track exits (5); where the tracks exits open in a direction at a substantially orthogonal angle to the longitudinal direction, where the track exits are disposed to permit movement therethrough substantially without friction and are disposed on opposing sides of the head, where the surfaces of the tracks guide the needles in a direction substantially orthogonal to a

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movement direction of the actuation device (see fig. 4), where the tracks have a shape corresponding to a memory shape of a portion of the needles, where the needles include a substantially linear proximal portion and an arcuate distal portion, where the arcuate shape of the portion is no greater than a circle and greater than a semi-circle (around 4c), where the material of the needles is a pseudo-elastic metal, where the actuation device has a rod (4) removably connected to or is integrally formed with (i.e., integrated with) the needles, where the retractor includes proximal stop (6), where the actuation device has a locking device (12) or an overstroke preventor, where the actuation device is a one-handed actuation device, where the head has an anchoring spike (2), where the actuation device selectively moves an actuator (8), where the needles are sized to control penetration depth into tissues, and where the needles are fixedly connected to the connector. However, Meeker does not disclose that the tracks are curved, where each track has an arcuate segment. Heil, Jr. et al. teach, at least in figure 5 and col. 8, lines 45-49; a device with a needle (131) guided through a curved track (139) with arcuate segments (141, 143). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Heil, Jr. et al., to modify the tracks of Meeker's device, so that each is curved and has an arcuate segment. Such a track would allow a needle to be extended out of the head through movement of the actuation device, while allowing smooth, slidable movement of the needle from the head.

However, neither Meeker nor Meeker in view of Heil, Jr. et al. discloses flexible needles that are of a shape memory material having a memory shape. Ley teaches, at

least in figure 2 and in col. 1, line 509 to col. 2, line 25 and col. 4, line 3 to col. 5, line 19; a retractor needle formed of a shape memory material (e.g., nitinol) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ley, to form the needles in the device of Meeker or Meeker in view of Heil, Jr. et al. out of a shape memory material having a memory shape. Such a material would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient. Additionally, Meeker or Meeker in view of Heil, Jr. et al. and Ley does not disclose that the two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

6. Claims 1, 5, 11, 15, 17, 19, 37, 39, 88, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittkampf (4,142,530) in view of Ley (5,514,076). Wittkampf discloses the invention substantially as claimed. Wittkampf discloses, at least in the figures and in col. 3, lines 14-32 and col. 4, lines 48-51; a retractor including a flexible body (31); a retraction device for manipulating or grasping an object, where the device has a head (30) connected to the distal end of the body; flexible needles (40, 38) of a resilient material; and an actuation device (32) connected to the proximal end of

the body, where the needles include a portion of arcuate shape, where the head includes a set of curved tracks (within 35), where each track has an arcuate segment and track exits each having a diameter at least as large as a needle diameter, where the head includes a shim (52), where a segment of the arcuate-shaped portion of a needle remains in a track while the needles are extended out of and retracted into the head, and where the arcuate-shaped portion corresponds to a shape of an arcuate segment. However, Wittkampff does not disclose the flexible needles are of a shape memory material having a memory shape. Ley teaches, at least in figures 2 and 3 and in col. 1, line 59 to col. 2, line 25 and col. 4, line 3 to col. 5, line 19; needles formed of a shape memory material (e.g., nitinol) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ley, to form the needles in the device of Wittkampff out of a shape memory material having a memory shape. Such a material is biocompatible and would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that any inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient. Wittkampff also does not disclose that the body and retraction device are sized to fit within the working channel of an endoscope. Nevertheless, it would have been a matter of obvious design choice to size the components of Wittkampff's device as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being with the level of ordinary skill in the art. Additionally, Wittkampff

does not disclose that the two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

7. Claims 39 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggs et al. (6,599,311) in view of Heil, Jr. et al. (5,514,174). Biggs et al. disclose the invention substantially as claimed. Biggs et al. disclose, at least in figures 8-10 and 24A-24B and in col. 3, lines 44-46; col. 11, lines 21-53; col. 16, lines 39-50; and col. 17, lines 52-66; a combination of a flexible endoscope (e.g., 34) having at least one working channel and a tissue retractor (e.g., 200) including a flexible body (e.g., 35), a retraction device including a head (e.g., 208), tracks (209) defined by the head, flexible needles (e.g., 204) of a shape memory material (e.g., nickel-titanium alloys) and including a portion with an arcuate shape; and an actuation device (e.g., 202) connected to a proximal end of the body, where upon actuation, the connector is moved to selectively extend the needles out of the head (see fig. 24B) and withdraw the needles into the head (see fig. 24A). However, Biggs et al. do not disclose that the head includes a set of curved tracks, where each track has a respective arcuate segment. Heil, Jr. et al. teach, at least in figure 5 and col. 8, lines 45-49; a device with a needle (131) guided through a curved track (139) with arcuate segments (141, 143). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in

view of Heil, Jr. et al., to modify the tracks of the device of Biggs et al., so that each is curved and has an arcuate segment. Such a track would allow a needle to be extended out of the head through movement of the actuation device, while allowing smooth, slidable movement of the needle from the head. Biggs et al. also do not disclose that the body and retraction device are sized to fit within the working channel of an endoscope. Nevertheless, it would have been a matter of obvious design choice to size the components of the device of Biggs et al. as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being with the level of ordinary skill in the art.

8. Claims 39-54, 58, 59, 61-65, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker (2,108,206) in view of Heil, Jr. et al. (5,514,174) and Ley (5,514,076), and further in view of Green (5,928,137). Meeker in view of Ley discloses substantially as claimed a tissue retractor including a rigid body and retraction device. However, Meeker in view of Ley does not disclose that the retractor is combined with a flexible endoscope having at least one working channel for receiving the body and the retraction device. Green teaches, at least in figures 1 and 5 and in col. 6, lines 49-65; a flexible endoscope having at least one working channel (e.g., 152) for receiving an endoscopic tool. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Green, to include a flexible endoscope with the device of Meeker in view of Ley. A flexible endoscope with at least one working channel would not only allow access for the device of Meeker in view of

Ley to a surgical site, it would also allow diagnosis and imaging of the site, especially where the site has narrow, even tortuous confines.

Response to Amendment

9. Applicant's arguments with respect to claims 1-66 and 83-89 have been considered but are moot in view of the new ground(s) of rejection. The indication of allowable subject matter in claims 17 and 19 is hereby withdrawn in view of new grounds of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lombardi (4,501,276) teaches a device with needles and a head with arcuate tracks.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

June 14, 2008